K042228

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NOV - 8 2004

510(k) Summary of Safety and Effectiveness – Traditional 510(k) for Modifications to the McKinley Beeline System

Date Prepared:	3 August 2004
Contact for questions:	Michelle Pratte
Trade Name:	Beeline Motiv, Propolis, PCA
Common Name:	Infusion Pump System & Kit
Classification Name:	Pump, Infusion
Classification Panel:	80 – General Hospital and Personal Use Device
Regulation Number:	Class II, 880.5725
Procode:	FRN
Original and previously cleared 510(k)s:	K990461 and K032642

Summary of Safety and Effectiveness for the Beeline System

Modifications to the existing device consist of an extension of the flow rate range, addition of medication reservoir volumes, addition of an indication for use, addition of bolus capability, and addition of intermittent flow capability.

The previously cleared device demonstrating substantial equivalence is the McKinley Beeline system (K032642).

Supporting predicate devices also demonstrating substantial equivalence is McKinley's Accufuser, Accufuser Plus & standard procedure kit (K033039), the I-Flow Elastomeric Pump (K040337), the Baxter Colleague Volumetric Pump (K010566), and the SIMS Deltec CADD-Prizm® Model 6101 Ambulatory Infusion System (K000842).

The Beeline system is intended for use as follows:

1. The Beeline system is intended for continuous and/or intermittent infusion of medication for general infusion use, including antibiotic delivery, chemotherapy and pain management. The Beeline system is indicated for intravenous, intra-arterial, enteral, subcutaneous, percutaneous and epidural infusion of medications or fluids requiring continuous and/or intermittent delivery at controlled infusion rates. The Beeline system is suitable for use as an ambulatory device and is intended for use in the hospital, home environment, and alternative care sites.
2. The Beeline system is intended to provide continuous and/or intermittent delivery of medication (such as local anesthetics or narcotics) to surgical wound sites

and/or close proximity to nerves for preoperative, perioperative and postoperative regional anesthesia and pain management. The Beeline system is also intended for patient-controlled infusion using the integrated bolus device.

3. The Beeline system is intended to significantly decrease narcotic use and pain when used to deliver local anesthetics to surgical wound sites or close proximity to nerves when compared with narcotic only pain management.

Summary Description of the Beeline System

The Beeline device consists of a spring-pressurized medication reservoir with a flowrate-controlling administration set. A spring applies force against a piston, pressurizing the medication. The administration set includes a flow restrictor component with controlled internal diameter and length. The flow rate at which medication is dispensed from the system is a function of the pressure applied to the medication and the dimensions of the flow restrictor component. The medication may be dispensed from the system continuously and/or intermittently.

The size of the reservoir and the amount of flow restriction are determined to yield a variety of product codes with differing infusion volumes and flow rates. The physician prescribes for a patient a flow rate and reservoir size based on the individual patient needs.

Administration sets may incorporate a bolus feature, which may be used alone or in conjunction with basal (continuous) or KVO (very low) flow. The bolus device consists of a dosage reservoir that is filled when activated manually. After the bolus device has been activated, the bolus volume is infused at a controlled flow rate. The bolus device is integrated into the administration set and allows patient-controlled administration of medication as needed.

A procedure kit option provides various components that facilitate setup and use of the Beeline system.

The Beeline system is intended for single patient use.

Conclusion: The modified Beeline system does not raise any new safety and efficacy concerns when compared to the original device that is already legally marketed. The Beeline system is substantially equivalent to the named predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 8 2004

Ms. Michelle Pratte
Project Engineer
McKinley Medical
4080 Youngfield Street
Wheat Ridge, Colorado 80033

Re: K042228
Trade/Device Name: Beeline Motiv, Propolis, PCA
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: August 3, 2004
Received: August 17, 2004

Dear Ms. Pratte:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

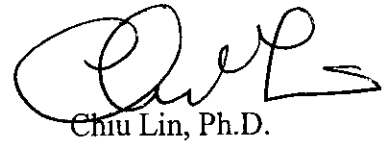
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042228

Device Name: Beeline System

Indications For Use:

1. The Beeline system is intended for continuous and/or intermittent infusion of medication for general infusion use, including antibiotic delivery, chemotherapy and pain management. The Beeline system is indicated for intravenous, intra-arterial, enteral, subcutaneous, percutaneous and epidural infusion of medications or fluids requiring continuous and/or intermittent delivery at controlled infusion rates. The Beeline system is suitable for use as an ambulatory device and is intended for use in the hospital, home environment, and alternative care sites.
2. The Beeline system is intended to provide continuous and/or intermittent delivery of medication (such as local anesthetics or narcotics) to surgical wound sites and/or close proximity to nerves for preoperative, perioperative and postoperative regional anesthesia and pain management. The Beeline system is also intended for patient-controlled infusion using the integrated bolus device.
3. The Beeline system is intended to significantly decrease narcotic use and pain when used to deliver local anesthetics to surgical wound sites or close proximity to nerves when compared with narcotic only pain management.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K042228